



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :  A61B 17/36		(11) International Publication Number: <b>WO 91/13592</b>  (43) International Publication Date: 19 September 1991 (19.09.91)
<p>(21) International Application Number: PCT/US91/00057</p> <p>(22) International Filing Date: 3 January 1991 (03.01.91)</p> <p>(30) Priority data: 492,717 13 March 1990 (13.03.90) US</p> <p>(71) Applicant: THE REGENTS OF THE UNIVERSITY OF CALIFORNIA [US/US]; 300 Lakeside Drive, 22nd Floor, Oakland, CA 94612-3550 (US).</p> <p>(72) Inventors: GUGLIELMI, Guido ; 11730 Sunset Boulevard, Apt. 129, Los Angeles, CA 90049 (US). SEPETKA, Ivan ; 1148 17th Avenue, Redwood City, CA 94063 (US).</p> <p>(74) Agent: DAWES, Daniel, L.; Beehler &amp; Pavitt, 3435 Wilshire Blvd., Suite 1100, Los Angeles, CA 90010 (US).</p>		<p>(81) Designated States: AT (European patent), AU, BB, BE (European patent), BG, BR, CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FI, FR (European patent), GB (European patent), GR (European patent), HU, IT (European patent), JP, KP, KR, LK, LU (European patent), MC, MG, MW, NL (European patent), NO, RO, SD, SE (European patent), SU.</p> <p>Published <i>With international search report.</i></p>
<p><b>(54) Title:</b> ENDOVASCULAR ELECTROLYTICALLY DETACHABLE GUIDEWIRE TIP</p> <p><b>(57) Abstract</b></p> <p>An artery, vein, aneurysm, vascular malformation or arterial fistula is occluded through endovascular electrothrombosis by the endovascular insertion of a platinum guidewire tip (30) into the vascular cavity followed by application of a positive current. The guidewire tip (30) is then separated from the guidewire by electrolytic separation of the tip from the guidewire (10). A portion (26) of the guidewire (10) connected between the tip (30) and the body of the guidewire (10) is comprised of stainless steel and exposed to the bloodstream so that upon continued application of a positive current to the exposed portion, the exposed portion is corroded away at least at one location and the tip (30) is separated from the body of guidewire (10). The guidewire (10) and the microcatheter are thereafter removed leaving the guidewire tip (30) embedded in the thrombus formed within the vascular cavity.</p>		

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CI	Côte d'Ivoire	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
DE	Germany	MC	Monaco	US	United States of America
DK	Denmark				

5

**ENDOVASCULAR ELECTROLYTICALLY DETACHABLE GUIDEWIRE TIP**

10

**Background of the Invention****1. Field of the Invention**

15       The invention relates to a method and apparatus for endovascular electrothrombic formation of thrombi in arteries, veins, aneurysms, vascular malformations and arteriovenous fistulas.

**20       2. Description of the Prior Art**

Approximately 25,000 intracranial aneurysms rupture every year in North America. The primary purpose of treatment for ruptured intracranial aneurysm is to prevent rebleeding. At the present time, three general methods of

treatment exist, namely an extravascular, endovascular and extra-endovascular approach.

The extravascular approach is comprised of surgery or microsurgery of the aneurysm or treatment site for the purpose of preserving the parent artery. This treatment is common with intracranial berry aneurysms. The methodology comprises the step of clipping the neck of the aneurysm, performing a suture-ligation of the neck, or wrapping the entire aneurysm. Each of these surgical procedures is performed by intrusive invasion into the body and performed from outside the aneurysm or target site. General anesthesia, craniotomy, brain retraction and arachnoid dissection around the neck of the aneurysm and placement of a clip are typically required in these surgical procedures.

Surgical treatment of vascular intracranial aneurysm can expect a mortality rate of 4-8% with a morbidity rate of 18-20%. Because of the mortality and morbidity rate expected, the surgical procedure is often delayed while waiting for the best surgical time with the result that an additional percentage of patients will die from the underlying disease or defect prior to surgery. For this reason the prior art has sought alternative means of treatment.

In the endovascular approach, the interior of the aneurysm is entered through the use of a microcatheter. Recently developed microcatheters, such as those shown by Engl son, "Catheter Guidewire", U.S. Patent 4,884,579 and as described in Engl son, "Catheter for Guidewire Tracking",

U.S. Patent 4,739,768 (1988), allow navigation into the cerebral arteries and entry into a cranial aneurysm.

In such procedures a balloon is typically attached to the end of the microcatheter and it is possible to introduce 5 the balloon into the aneurysm, inflate it, and detach it, leaving it to occlude the sac and neck with preservation of the parent artery. While endovascular balloon embolization of berry aneurysms is an attractive method in situations where an extravascular surgical approach is difficult, 10 inflation of a balloon into the aneurysm carries some risk of aneurysm rupture due to possible over-distention of portions of the sac and due to the traction produced while detaching the balloon.

While remedial procedures exist for treating a ruptured 15 aneurysm during classical extravascular surgery, no satisfactory methodology exists if the aneurysm breaks during an endovascular balloon embolization.

Furthermore, an ideal embolizing agent should adapt 20 itself to the irregular shape of the internal walls of the aneurysm. On the contrary, in a balloon embolization the aneurysmal wall must conform to the shape of the balloon. This may not lead to a satisfactory result and further increases the risk of rupture.

Still further, balloon embolization is not always 25 possible. If the diameter of the deflated balloon is too great to enter the intracerebral arteries, specially in the cases where there is a vasospasm, complications with ruptured

intracranial aneurysms may occur. The procedure then must be deferred until the spasm is resolved and this then incurs a risk of rebleeding.

In the extra-intravascular approach, an aneurysm is 5 surgically exposed or stereotactically reached with a probe. The wall of the aneurysm is then perforated from the outside and various techniques are used to occlude the interior in order to prevent it from rebleeding. These prior art techniques include electrothrombosis, isobutyl-cyanoacrylate 10 embolization, hog-hair embolization and ferromagnetic thrombosis.

In the use of electrothrombosis for extra-intravascular treatment the tip of a positively charged electrode is inserted surgically into the interior of the aneurysm. An 15 application of the positive charge attracts white blood cells, red blood cells, platelets and fibrinogen which are typically negatively charged at the normal pH of the blood. The thrombic mass is then formed in the aneurysm about the tip. Thereafter, the tip is removed. See Mullan, 20 "Experiences with Surgical Thrombosis of Intracranial Berry Aneurysms and Carotid Cavernous Fistulas", J. Neurosurg., Vol. 41, December 1974; Hosobuchi, "Electrothrombosis Carotid-Cavernous Fistula", J. Neurosurg., Vol. 42, January 1975; Araki et al., "Electrically Induced Thrombosis for the 25 Treatment of Intracranial Aneurysms and Angiomas", Excerpta Medica International Congress Series, Amsterdam 1965, Vol. 110, 651-654; Sawyer et al., "Bio-Electric Phenomena as an

Etiological Factor in Intravascular Thrombosis", Am. J. Physiol., Vol. 175, 103-107 (1953); J. Piton et al., "Selective Vascular Thrombosis Induced by a Direct Electrical Current; Animal Experiments", J. Neuroradiology, Vol. 5, 5 pages 139-152 (1978). However, each of these techniques involves some type of intrusive procedure to approach the aneurysm from the exterior of the body.

The prior art has also devised the use of a liquid adhesive, isobutyl-cyanoacrylate (IBCA) which polymerizes rapidly on contact with blood to form a firm mass. The liquid adhesive is injected into the aneurysm by puncturing the sac with a small needle. In order to avoid spillage into the parent artery during IBCA injection, blood flow through the parent artery must be momentarily reduced or interrupted. 10 Alternatively, an inflated balloon may be placed in the artery at the level of the neck of the aneurysm for injection. In addition to the risks caused by temporary blockage of the parent artery, the risks of seepage of such a polymerizing adhesive into the parent artery exists, if it is 15 not completely blocked with consequent occlusion of the artery. 20

Still further, the prior art has utilized an air gun to inject hog hair through the aneurysm wall to induce internal thrombosis. The success of this procedure involves exposing 25 the aneurysm sufficiently to allow air gun injection and has not been convincingly shown as successful for thrombic formations.

Ferromagnetic thrombosis in the prior art in extra-intravascular treatments comprises the stereotactic placement of a magnetic probe against the sac of the aneurysm followed by injection into the aneurysm by an injecting needle of iron microspheres. Aggregation of the microspheres through the extravascular magnet is followed by interneuysmatic thrombus. This treatment has not been entirely successful because of the risk of fragmentation of the metallic thrombus when the extravascular magnet is removed. Suspension of the iron powder in methyl methymethacrylate has been used to prevent fragmentation. The treatment has not been favored, because of the need to puncture the aneurysm, the risk of occlusion of the parent artery, the use of unusual and expensive equipment, the need for a craniectomy and general anesthesia, and the necessity to penetrate cerebral tissue to reach the aneurysm.

Endovascular coagulation of blood is also well known in the art and a device using laser optically generated heat is shown by O'Reilly, "Optical Fiber with Attachable Metallic Tip for Intravascular Laser Coagulation of Arteries, Veins, Aneurysms, Vascular Malformation and Arteriovenous Fistulas", U.S. Patent 4,735,201 (1988). See also, O'Reilly et al., "Laser Induced Thermal Occlusion of Berry Aneurysms: Initial Experimental Results", Radiology, Vol. 171, No. 2, pages 471-74 (1989). O'Reilly places a tip into an aneurysm by means of an endovascular microcatheter. The tip is adhesively bonded to a optic fiber disposed through the microcatheter.

Optical energy is transmitted along the optic fiber from a remote laser at the proximal end of the microcatheter. The optical energy heats the tip to cauterize the tissue surrounding the neck of the aneurysm or other vascular opening to be occluded. The catheter is provided with a balloon located on or adjacent to its distal end to cut off blood flow to the site to be cauterized and occluded. Normally, the blood flow would carry away the heat at the catheter tip, thereby preventing cauterization. The heat in the tip also serves to melt the adhesive used to secure the tip to the distal end of the optical fiber. If all goes well, the tip can be separated from the optical fiber and left in place in the neck of the aneurysm, provided that the cauterization is complete at the same time as the hot melt adhesive melts.

A thrombus is not formed from the heated tip. Instead, blood tissue surrounding the tip is coagulated. Coagulation is a denaturation of protein to form a connective-like tissue similar to that which occurs when the albumen of an egg is heated and coagulates from a clear running liquid to an opaque white solid. The tissue characteristics and composition of the coagulated tissue is therefore substantially distinct from the thrombosis which is formed by the thrombotic aggregation of white and red blood cells, platelets and fibrinogen. The coagulative tissue is substantially softer than a thrombic mass and can therefore more easily be dislodged.

O'Reilly's device depends at least in part upon the successful cauterization timed to occur no later than the detachment of the heat tip from the optic fiber. The heated tip must also be proportionally sized to the neck of the aneurysm in order to effectively coagulate the tissue surrounding it to form a blockage at the neck. It is believed that the tissue in the interior of the aneurysm remains substantially uncoagulated. In addition, the hot melt adhesive attaching the tip to the optic fiber melts and is dispersed into the adjacent blood tissue where it resolidifies to form free particles within the intracranial blood stream with much the same disadvantages which result from fragmentation of a ferromagnetic electrothrombosis.

Therefore, what is needed is an apparatus and methodology which avoids each of the shortcomings and limitations of the prior art discussed above.

#### Brief Summary of the Invention

A method for forming a thrombus within a vascular cavity comprising the steps of endovascularly disposing a guidewire near an endovascular opening into the vascular cavity. A distal tip of the guidewire is disposed into the vascular cavity. An electrical signal is applied to the distal tip within the vascular cavity to form a thrombus within the vascular cavity about the distal tip. The distal tip is detached from the guidewire to leave the distal tip within

the vascular cavity and the thrombus electrically formed within the vascular cavity.

As a result, electrical formation of a thrombus is completely endovascularly formed.

5       The step of disposing the distal tip in the vascular cavity further comprises the step of substantially occupying the vascular cavity with the distal tip.

In one embodiment the step of substantially occupying the vascular cavity comprises the step of filling the 10 vascular cavity with a long and pliable length of the distal tip.

The step of detaching the distal tip from the guidewire comprises the step of electrolytically detaching the distal tip from the guidewire.

15      The step of electrolytically detaching the distal tip from the guidewire comprises the step of electrolytically disintegrating at least one portion of a connecting segment extending between the guidewire and the distal tip.

The step of electrolytically disintegrating the 20 connecting segment comprises the step of electrolytically corroding away at least a portion of a coil segment.

The step of electrolytically corroding the coil segment comprises the step of electrolytically disintegrating a stainless steel coil segment.

25      The step of applying an electrical signal to the distal tip to form the thrombus comprises the step of applying a positive direct current for a first predetermined time

period. The tip can be detached in at least three different ways. First, the same current for forming the thrombosis may also simultaneously be used to detach the tip. Second, the current, which forms the thrombosis or initiates the continuing formation of the thrombosis during a following period of no current, is followed by a current of the same or different magnitude during a second time period to effect detachment. Third, the thrombosis is formed during a time period during which the disintegratable portion of the tip is arranged and configured not to be exposed to the blood. The guidewire is then repositioned so the disintegratable portion is exposed to electrolytic disintegration in the blood by application of the same or different level of current for an additional time period to effect detachment.

The invention is also a guidewire for use in electrothrombosis and used in combination with a microcatheter comprising a core wire. The core wire has a distal portion susceptible to electrolytic disintegration in blood. A tip portion is coupled to the distal portion of the core wire. The tip portion is provided for endovascular insertion within a vascular cavity.

As a result, endovascular electrothrombosis is achieved.

The distal portion is an exposed stainless steel segment.

The stainless steel segment comprises a coil connected at its proximate end to the core wire and connected at its

distal end to the tip portion of the guidewire.

In one embodiment the core wire is extended in a threadlike portion concentrically within the stainless steel coil from the distal end of the stainless steel coil to where  
5 the stainless steel coil is connected to the tip portion of the guidewire.

In another embodiment the coil defines an interior space. The interior space is free and unreinforced.

10 The tip portion is a long and substantially pliable segment and is comprised of a material not susceptible to electrolytic disintegration within blood.

In one embodiment the long and pliable segment has a length sufficient to substantially fill the vascular cavity when inserted therein.

15 In another embodiment the long and pliable segment is prebiased to form a helix when extended from the microcatheter. The helix may have a conical envelope or a cylindrical envelope.

20 The invention can better be visualized by now turning to the following drawings wherein like elements are referenced by like numerals.

#### Brief Description of the Drawings

25 Figure 1 is an enlarged partially cross-sectioned side view of a first embodiment of the distal end of the guidewire and guidewire tip of the invention.

Figure 2 is an enlarged longitudinal cross section of a second embodiment of the guidewire and guidewire tip of the invention.

5 Figure 3 is an enlarged side view of a third embodiment of the invention with a microcatheter portion cut away in a longitudinal cross-sectional view.

Figure 4 is a simplified depiction of the guidewire of Figure 3 shown disposed within a simple cranial aneurysm.

10 Figure 5 is a depiction of the microguidewire of Figure 4 shown after electrolytic detachment of the guidewire tip.

#### Detailed Description of the Preferred Embodiments

15 An artery, vein, aneurysm, vascular malformation or arterial fistula is occluded through endovascular electrothrombosis by the endovascular insertion of a platinum guidewire tip into the vascular cavity followed by application of a positive current. The guidewire tip is then  
20 separated from the guidewire by electrolytic separation of the tip from the guidewire. A portion of the guidewire connected between the tip and the body of the guidewire is comprised of stainless steel and exposed to the bloodstream so that upon continued application of a positive current to the exposed portion, the exposed portion is corroded away at least at one location and the tip is separated from the body of the guidewire. The guidewire and the microcatheter are  
25

thereafter removed leaving the guidewire tip embedded in the thrombus formed within the vascular cavity.

Figure 1 is an enlarged side view of a first embodiment of the distal end of the guidewire and guidewire tip shown in partial cross-sectional view. A conventional Teflon laminated or similarly insulated stainless steel guidewire 10 is disposed within a protective microcatheter (not shown). Stainless steel guidewire 10 is approximately 0.010 - 0.020 inch (0.254-0.508 mm) in diameter. In the illustrated embodiment, guidewire 10 is tapered at its distal end to form a conical section 12 which joins a section 14 of reduced diameter which extends longitudinally along a length 16 of guidewire 10. Section 16 then narrows gradually down to a thin threadlike portion 18 beginning at a first bonding location 20 and ending at a second bonding location 22.

The stainless steel guidewire 10, comprised of that portion disposed within the microcatheter body, tapered section 12, reduced diameter section 16 and threadlike section 18, is collectively referred to as a core wire which typically is 50 - 300 cm. in length.

In the illustrated embodiment the portion of the core wire extending from tapered section 12 to second bonding location 22 is collectively referred to as the grinding length and may typically be between 20 and 50 cm. in length.

Reduced diameter portion 14 and at least part of sections 12 and first bonding location 20 may be covered with an insulating Teflon laminate 24 which encapsulates the

underlying portion of guidewire 10 to prevent contact with the blood.

A stainless steel coil 26 is soldered to the proximate end of threadlike portion 18 of guidewire 10 at first bonding location 20. Stainless steel coil 26 is typically 3 to 10 cm. in length and like guidewire 10 has a diameter typically between 0.010 to 0.020 inch (0.254-0.508 mm).

The distal end of stainless steel coil 26 is soldered to the distal end of threadlike portion 18 of guidewire 10 and 10 to the proximal end of a platinum secondary coil 28 at second bonding location 22. Secondary coil 28 itself forms a spiral or helix typically between 2 to 10 mm. in diameter. The helical envelope formed by secondary coil 28 may be cylindrical or conical. Like guidewire 10 and stainless 15 steel coil 26, secondary coil 28 is between approximately 0.010 and 0.020 inch (0.254-0.508 mm) in diameter. The diameter of the wire itself forming stainless steel coil 26 and coil 28 is approximately between 0.001 - 0.005 inch.

The distal end of secondary coil 28 is provided with a 20 platinum soldered tip 30 to form a rounded and smooth termination to avoid puncturing the aneurysm or tearing tissue.

Although prebiased to form a cylindrical or conical envelope, secondary coil 28 is extremely soft and its overall 25 shape is easily deformed. When inserted within the microcatheter (not shown), secondary coil 28 is easily straightened to lie axially within the microcatheter. Once

disposed out of the tip of the microcatheter, secondary coil 28 forms the shape shown in Figure 1 and may similarly be loosely deformed to the interior shape of the aneurysm.

As will be described below in greater detail in connection with the third embodiment of Figure 3, after placement of secondary coil 28 within the interior of the aneurysm, a direct current is applied to guidewire 10 from a voltage source exterior to the body. The positive charge on secondary coil 28 within the cavity of the aneurysm causes a thrombus to form within the aneurysm by electrothrombosis. Detachment of the tip occurs either: (1) by continued application of current for a predetermined time when the portion 18 is exposed to blood; or (2) by movement of the wire to expose portion 18 to blood followed by continued current application for a predeteremined time. Ultimately, both threadlike portion and stainless steel coil 26 will be completely disintegrated at least at one point, thereby allowing guidewire 10 to be withdrawn from the vascular space while leaving secondary coil 28 embedded within the thrombus formed within the aneurysm.

Figure 2 illustrates in enlarged partially cross-sectional view a second embodiment of the invention. Stainless steel core 32 terminates in a conical distal portion 34. Stainless steel coil 36, shown in cross-sectional view, is soldered to distal portion 34 of guidewire 32 at bonding location 38. The opposing end of the stainless steel coil 36 is provided with a soldered, rounded platinum

tip 40. In the illustrated embodiment, stainless steel core wire 32 is approximately 0.010 inch in diameter with the length of stainless steel coil 36 being approximately 8 cm. with the longitudinal length of platinum tip 40 being between 5 3 and 10 mm. The total length of guidewire 32 from tip 40 to the proximate end is approximately 150 cm.

The embodiment of Figure 2 is utilized in exactly the same manner as described above in connection with Figure 1 to form a thrombic mass within an aneurysm or other vascular cavity. The embodiment of Figure 2 is distinguished from that shown in Figure 1 by the absence of the extension of stainless core 32 through coil 36 to tip 40. In the case of the embodiment of Figure 2 no inner core or reinforcement is provided within stainless steel coil 36. Threadlike portion 10 18 is provided in the embodiment of Figure 1 to allow increased tensile strength of the guidewire. However, a degree of flexibility of the guidewire is sacrificed by the inclusion even of threadlike tip 18, so that the embodiment of Figure 2 provides a more flexible tip, at least for that 15 portion of the microguidewire constituting the stainless steel coil 36.

It is expressly understood that the helical secondary coil tip of the embodiment of Figure 1 could similarly be attached to stainless steel coil 36 of the embodiment of 20 Figure 2 without departing from the spirit and scope of the invention.

Thinned and threadlike portion guidewires disposed concentrically within coiled portions are well known and are shown in Antoshkiw, "Disposable Guidewire", U.S. Patent 3,789,841 (1974); Sepetka et al., "Guidewire Device", U.S. Patent 4,832,047 (1989); Engleson, "Catheter Guidewire", U.S. Patent 4,884,579 (1989); Samson et al., "Guidewire for Catheters", U.S. Patent 4,538,622 (1985); and Samson et al., "Catheter Guidewire with Short Spring Tip and Method of Using the Same", U.S. Patent 4,554,929 (1985).

Turn now to the third embodiment of the invention as shown in Figure 3. Figure 3 shows an enlarged side view of a guidewire, generally denoted by reference numeral 42, disposed within a microcatheter 44 shown in cross-sectional view. Like the embodiment of Figure 1, a stainless steel coil 46 is soldered to a conical portion 48 of guidewire 22 at a first bonding location 50. A thin threadlike extension 52 is then longitudinally disposed within stainless steel coil 46 to a second bonding location 54 where stainless steel guidewire 46 and threadlike portion 52 are soldered to a soft platinum coil 56. Platinum coil 56 is not prebiased, nor does it contain any internal reinforcement, but is a free and open coil similar in that respect to stainless steel coil 36 of the embodiment of Figure 2.

However, platinum coil 56 is particularly distinguished by its length of approximately 1 to 50 cm. and by its flexibility. The platinum or platinum alloy used is particularly pliable and the diameter of the wire used to

form platinum coil 56 is approximately 0.001 - 0.005 inch in diameter. The distal end of platinum coil 56 is provided with a smooth and rounded platinum tip 58 similar in that respect to tips 30 and 40 of Figures 1 and 2, respectively.

5 When coil 56 is disposed within microcatheter 54, it lies along the longitudinal lumen 60 defined by microcatheter 44. The distal end 62 of microcatheter 60 is then placed into the neck of the aneurysm and the guidewire 42 is advanced, thereby feeding tip 58 in platinum coil 56 into 10 aneurysm 64 until bonding location 50 resides in the neck of the aneurysm as best depicted in the diagrammatic cross-sectional view of Figure 4.

Figure 4 illustrates the insertion of the embodiment of Figure 3 within a vessel 66 with distal tip of microcatheter 15 44 positioned near neck 68 of aneurysm 64. Coil 56 is fed into aneurysm 64 until at least a portion of stainless steel coil 46 is exposed beyond the distal tip 62 of microcatheter 44. A positive electric current of approximately 0.01 to 2 milliamps at 0.1 - 6 volts is applied to guidewire 42 to form 20 the thrombus. Typically a thrombus will form within three to five minutes. The negative pole 72 of voltage source 70 is typically placed over and in contact with the skin.

After the thrombus has been formed and the aneurysm completely occluded, tip 58 and coil 56 are detached from 25 guidewire 42 by electrolytic disintegration of at least one portion of stainless steel coil 46. In the illustrated embodiment this is accomplished by continued application of

current until the total time of current application is almost approximately four minutes.

At least one portion of stainless steel coil 46 will be completely dissolved through by electrolytic action within 3 5 to 10 minutes, usually about 4 minutes. After separation by electrolytic disintegration, guidewire 42, microcatheter 44 and the remaining portion of coil 46 still attached to guidewire 42 are removed from vessel 66, leaving aneurysm 64 completely occluded as diagrammatically depicted in Figure 5 10 by thrombus 74. It will be appreciated that the time of disintegration may be varied by altering the dimensions of the portions of the wire and/or the current.

The process is practiced under fluoroscopic control with local anesthesia at the groin. A transfemoral microcatheter 15 is utilized to treat the cerebral aneurysm. The platinum is not affected by electrolysis and the remaining portions of the microcatheter are insulated either by a Teflon lamination directly on guidewire 42 and/or by microcatheter 44. Only the exposed portion of the guidewire 46 is affected by the 20 electrolysis.

It has further been discovered that thrombus 74 continues to form even after detachment from guidewire 42. It is believed that a positive charge is retained on or near coil 56 which therefore continues to attract platelets, white 25 blood cells, red blood cells and fibrinogen within aneurysm 64.

Many alterations and modifications may be made by those having ordinary skill in the art without departing from the spirit and scope of the invention. Therefore, it must be understood that the shape of the tip or distal platinum coil used in combination with the guidewire according to the invention may be provided with a variety of shapes and envelopes. In addition thereto, the composition of the microguidewire tip may be made of elements other than platinum including stainless steel, beryllium, copper and various alloys of the same with or without platinum. Still further, the diameter of the guidewire, various of the guidewire described above and the stainless steel coil immediately proximal to the detachable tip may be provided with differing diameters or cross sections to vary the times and current magnitudes necessary in order to effectuate electrolytic detachment from the tip. Still further, the invention may include conventional electronics connected to the proximal end of the guidewire for determining the exact instant of detachment of the distal tip from the guidewire.

Therefore, the illustrated embodiment has been set forth only for the purposes of clarity and example and should not be taken as limiting the invention as defined by the following claims, which include all equivalent means whether now known or later devised.

1           1. A method for forming a thrombus within a  
vascular cavity having blood disposed therein comprising  
the steps of:

endovascularly disposing a guidewire near an  
5 endovascular opening into said vascular cavity;

disposing a distal tip of said guidewire into  
said vascular cavity;

applying a first electrical signal to said  
distal tip within said vascular cavity to form a thrombus  
10 within said vascular cavity about said distal tip; and

electrolytically detaching said distal tip from  
said guidewire to leave said distal tip within said  
vascular cavity and said thrombus electrically formed  
within said vascular cavity,

15           whereby electrical formation of a thrombus is  
completely endovascularly formed.

1           2. The method of Claim 1 where said step of  
disposing said distal tip in said vascular cavity further  
comprises the step of substantially occupying said  
vascular cavity with said distal tip.

1           3. The method of Claim 2 where said step of  
substantially occupying said vascular cavity comprises  
the step of filling said vascular cavity with a long and  
pliable length of said distal tip.

1           4. The method of Claim 1 wherein said step of  
detaching said distal tip from said guidewire comprises  
the step of electrolytically detaching said distal tip  
from said guidewire.

1           5. The method of Claim 4 where said step of  
electrolytically detaching said distal tip from said  
guidewire comprises the step of electrolytically  
disintegrating at least one portion of a connecting  
5 segment extending between said guidewire and said distal  
tip.

1           6. The method of Claim 5 where said step of  
electrolytically disintegrating said connecting segment  
comprises the step of electrolytically corroding away at  
least a portion of a coil segment.

1           7. The method of Claim 6 where said step of  
electrolytically corroding said coil segment comprises  
the step of electrolytically disintegrating a stainless  
steel coil segment.

1           8. The method of Claim 1 wherein said step of  
applying an electrical signal to said distal tip to form  
said thrombus comprises the step of applying a positive  
direct current for a first predetermined time period.

1               9. The method of Claim 1 wherein said step of  
detaching said distal tip from said guidewire comprises  
the step of applying a positive direct current for an  
additional predetermined time period.

1               10. The method of Claim 8 wherein said step of  
detaching said distal tip from said guidewire comprises  
the step of applying a positive direct current for an  
additional predetermined time period separate from said  
5 first predetermined time period.

1               11. The method of Claim 8 wherein said step of  
detaching the location of detachment of said tip from  
said guidewire is unexposed during said first  
predetermined time period, and is exposed to blood during  
5 said additional predetermined time period.

1               12. A guidewire for use in electrothrombosis  
used in combination with a microcatheter comprising:  
                  a core wire, said core wire having a distal  
portion susceptible to electrolytic disintegration in  
5 blood; and  
                  a tip portion coupled to said distal portion of  
said core wire, said tip portion for endovascular  
insertion within a vascular cavity,  
                  whereby endovascular electrothrombosis can be  
10 performed.

1           13. The guidewire of Claim 12 wherein said  
distal portion is an exposed stainless steel segment.

1           14. The guidewire of Claim 13 wherein said  
stainless steel segment comprises a coil connected at its  
proximate end to said core wire and connected at its  
distal end to said tip portion of said guidewire.

1           15. The guidewire of Claim 14 wherein said  
core wire is extended in a threadlike portion  
concentrically within said stainless steel coil from said  
distal end of said stainless steel coil to where said  
5       stainless steel coil is connected to said tip portion of  
said guidewire.

1           16. The guidewire of Claim 14 wherein said  
coil defines an interior space, said interior space being  
free and unreinforced.

1           17. The guidewire of Claim 12 wherein said tip  
portion is a long and substantially pliable segment and  
is comprised of a metal not susceptible to electrolytic  
disintegration within blood.

1           18. The guidewire of Claim 12 wherein said tip  
portion is comprised of 479 platinum alloy.

1               19. The guidewire of Claim 17 wherein said long and pliable segment has a length sufficient to substantially fill said vascular cavity when inserted therein.

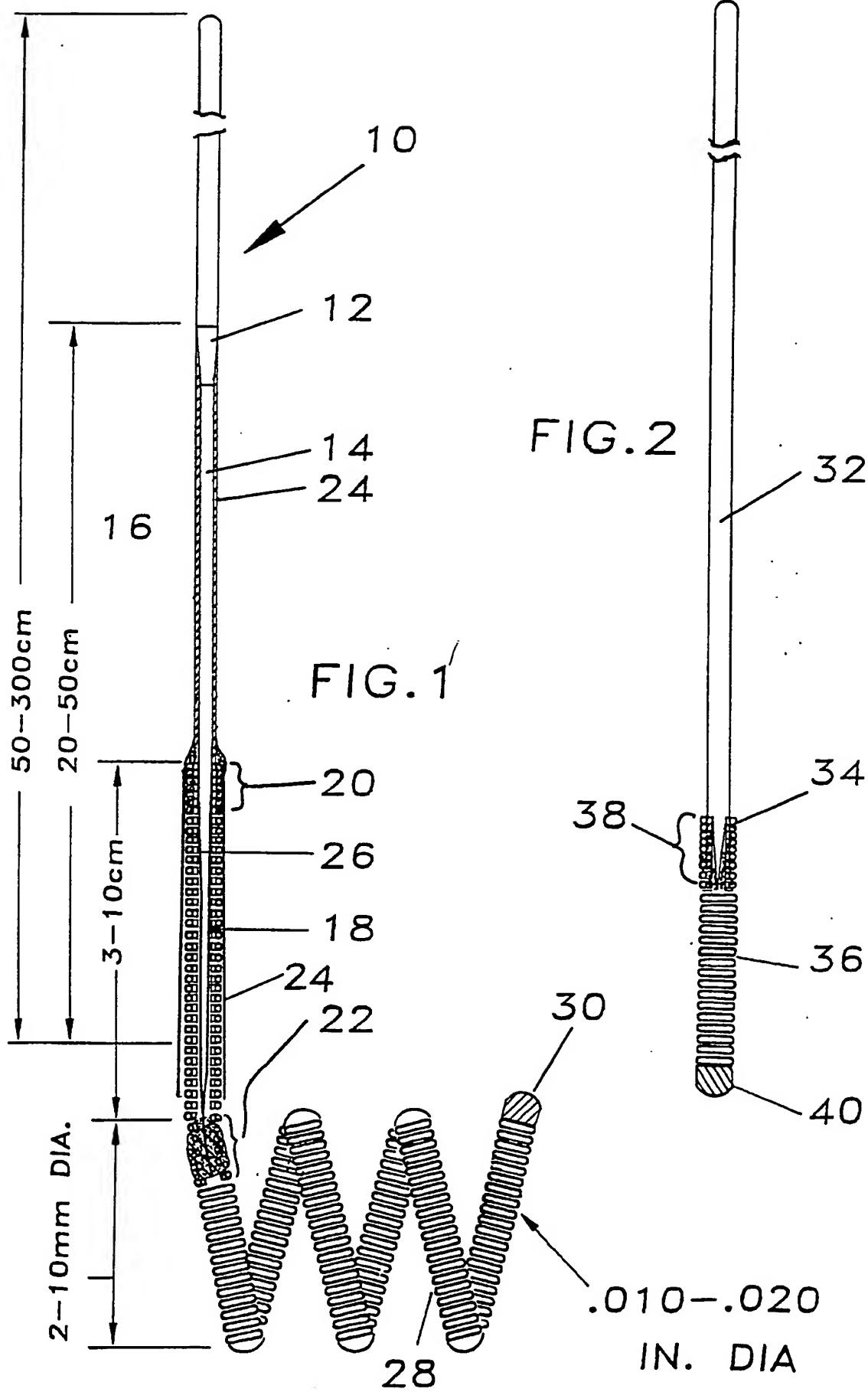
1               20. The guidewire of Claim 17 wherein said long and pliable segment is prebiased to form a helix when extended from said microcatheter.

1               21. The guidewire of Claim 20 wherein said helix has a conical envelope.

1               22. The guidewire of Claim 20 wherein said helix has a cylindrical envelope.

1               23. The method of Claim 1 wherein said step of disposing said tip comprises the step of disposing said guidewire in a first position relative to said vascular cavity so that a disintegratable portion of said tip  
5               remains insulated from said blood during application of said first electrical signal to said tip, and where said step of detaching comprises moving said disintegratable portion of said tip to a second position where said disintegratable portion is exposed to said blood,  
10 applying a second electrical signal to said

11 disintegratable portion to electrolytically dissolve said  
disintegratable portion in said blood.



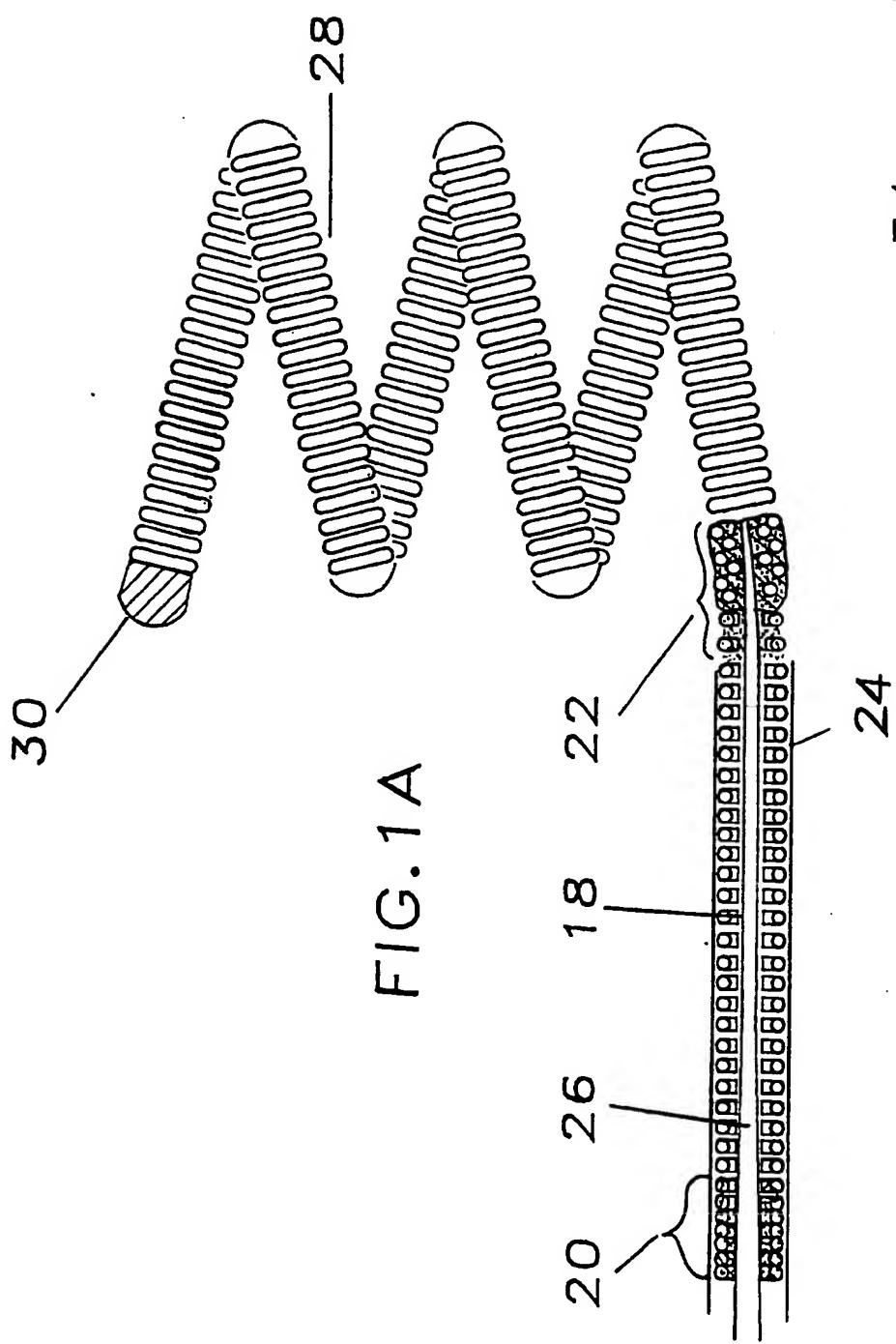
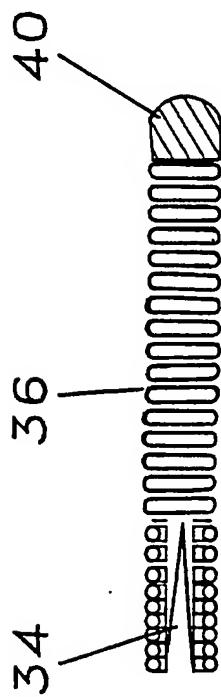


FIG. 2A



3/5

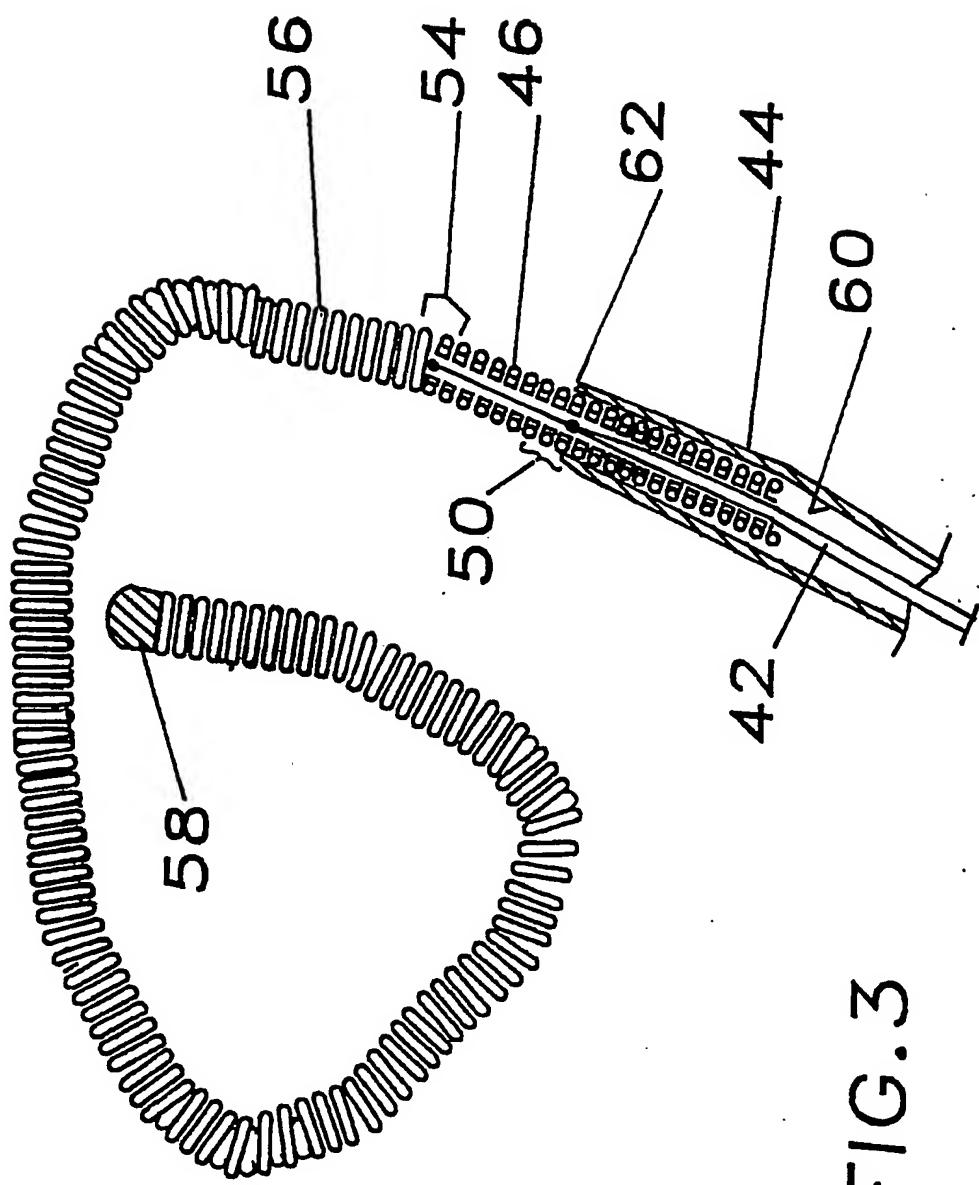
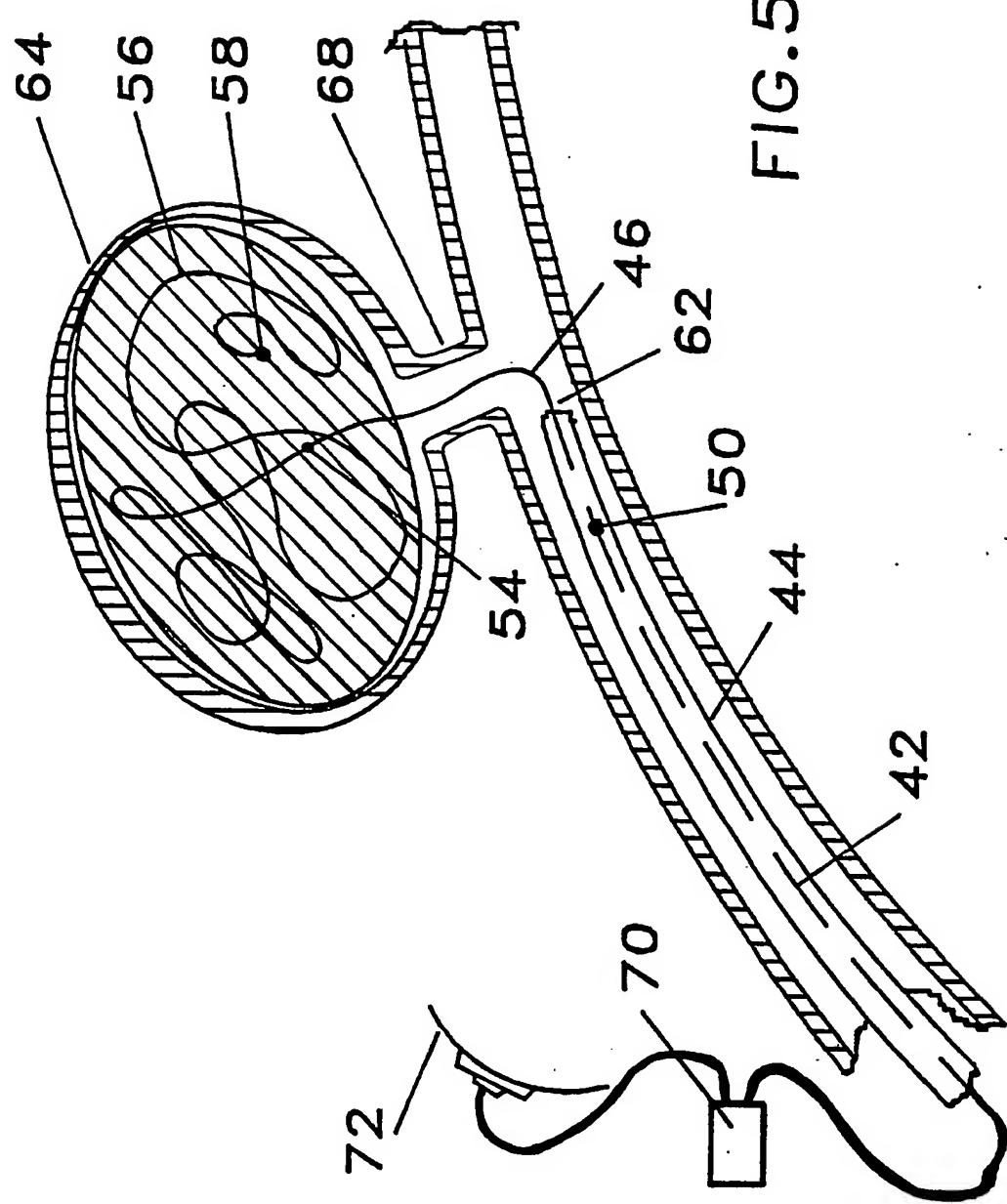
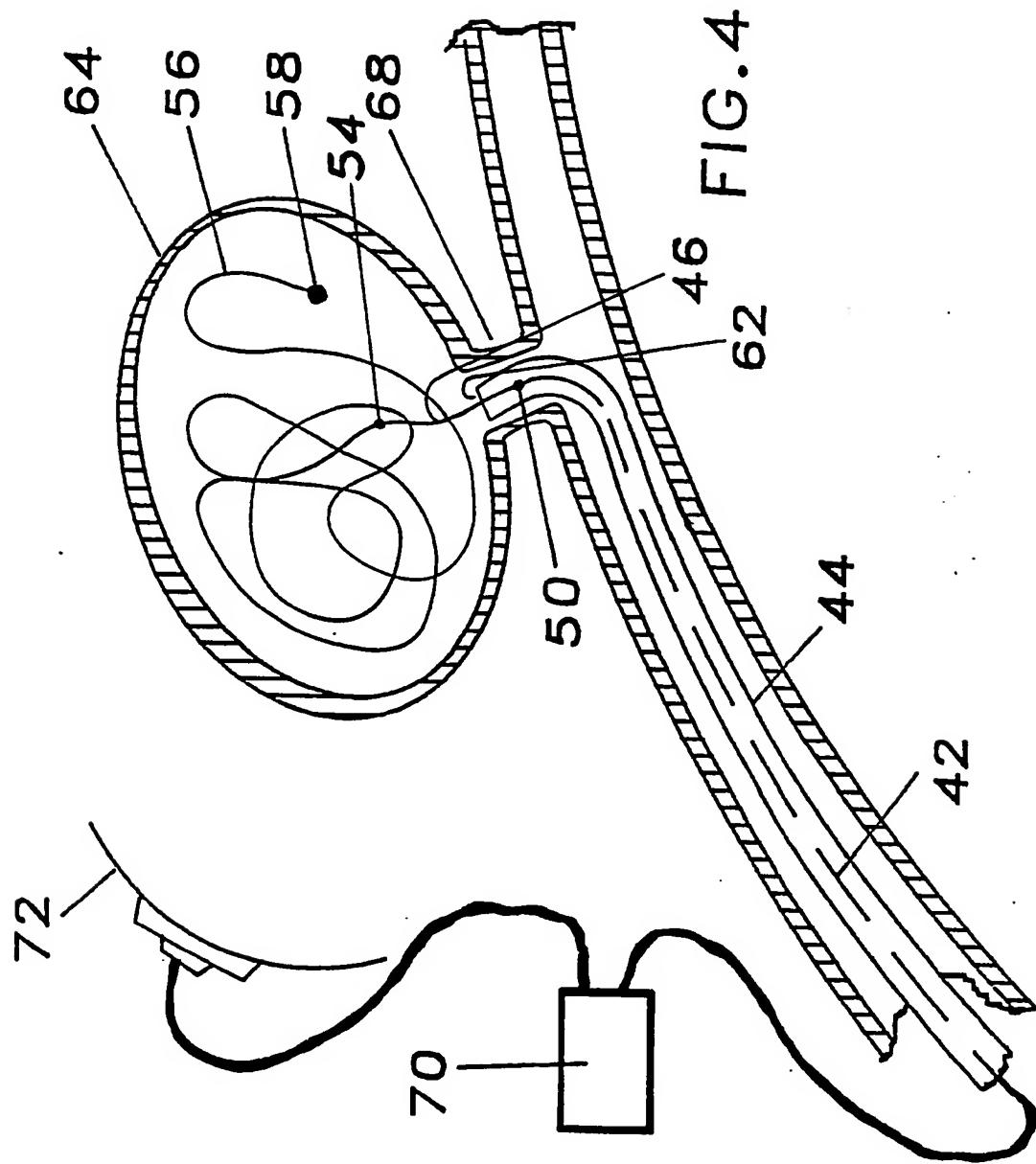


FIG. 3

5/5



4/5



# INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/00057

## I. CLASSIFICATION & SUBJECT MATTER (if several classification symbols apply, indicate all) <sup>3</sup>

According to International Patent Classification (IPC) or to both National Classification and IPC

**IPC (5): A61B 17/36**

**U.S. CL: 606/32, 41 128/772, 786**

## II. FIELDS SEARCHED

Minimum Documentation Searched <sup>4</sup>

Classification System	Classification Symbols
U.S.	606/32, 41, 49 128/772, 784, 786

Documentation Searched other than Minimum Documentation  
to the Extent that such Documents are Included in the Fields Searched <sup>5</sup>

## III. DOCUMENTS CONSIDERED TO BE RELEVANT <sup>14</sup>

Category <sup>6</sup>	Citation of Document, <sup>14</sup> with indication, where appropriate, of the relevant passages <sup>14</sup>	Relevant to Claim No. <sup>14</sup>
A	US, A, 4,522,205 (TAYLOR) 11 June 1985 See entire document.	1
X	US, A, 4,748,986 (MORRISON) 07 June 1988 See entire document.	12-19
A	WO, A, 8,801,851 (YAMANASHI) 24 March 1988 See entire document.	1

\* Special categories of cited documents: <sup>15</sup>

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in this art.

"Z" document member of the same patent family

## IV. CERTIFICATION

Date of the Actual Completion of the International Search <sup>7</sup>

23 APRIL 1991

International Searching Authority <sup>8</sup>

ISA/US

Date of Mailing of this International Search Report <sup>9</sup>

04 JUN 1991

Signature of Authorized Officer <sup>10</sup>

LEE S. COHEN